UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/584,073 | 09/20/2006 | Jan Utas | 0104-0583PUS1 | 3384 |

2292 7590 12/14/2010
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| EXAMINER | |
|---|---|
| HAND, MELANIE JO | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3761 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 12/14/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/584,073 | UTAS ET AL. | |
| | Examiner | Art Unit | |
| | MELANIE J. HAND | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/06,7/8/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. The applicant is advised that future amendments to the claims must contain a statement at the top of the first page stating that that amendment replaces all previous amendments to the claims. The examiner has examined on the merits herein the set of claims that she believes to be the most recent.

### *Priority*

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Information Disclosure Statements*

3. The information disclosure statements (IDS) submitted on June 22, 2006 and July 8, 2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### *Claim Objections*

4. Claim 35 is objected to because of the following informalities: the phrase " n remarkably efficient" appearing at the end of claim 35 appears to be a typographical error that is not intended to be part of the claim language. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4, 5, 11, 18, 19, 24, 25, 30, 31, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 4, 5, 11, 18, 19, 24, 25, 30, 31, 34 and 35 all recite a broad recitation, e.g. “exceeding 700 mOsm/$dm^3$”, and then also recite, e.g. “preferably exceeding 800 mOsm/$dm^3$” which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 17 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Johansson et al (EP 217771 A1).

With respect to **claim 17:** Johansson discloses a wetting fluid for activation of a hydrophilic surface layer in order to produce a low-friction surface character of said hydrophilic surface layer by treatment by said the wetting fluid, characterized in that the wetting fluid comprises at least one dissolved osmolality- increasing compound, namely 2 % w/v sodium chloride (NaCl) wherein the total concentration of the osmolality-increasing compound is 600 mOsm/$dm^3$, which exceeds 600 mOsm/$dm^3$. ('771, Abstract)

With respect to **claim 33:** Johansson discloses use of a wetting fluid solution containing 2% w/v sodium chloride for activation of a catheter having on its surface, on at least an insertable part thereof, a hydrophilic surface layer providing low-friction surface character of the catheter by treatment with said wetting fluid, characterized in that the wetting fluid comprises at least one dissolved osmolality-increasing compound, wherein the total concentration of the dissolved osmolality-increasing compounds is 680 mOsm/$dm^3$, i.e. it exceeds 600 mOsm/dm3.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3, 4-6, 16, 18-20, 24-26, 30, 31, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israelsson (WO 97/26937 A1) in view of Bongard (see attached PTO-892 form for full citation).

With respect to **claim 1:** Israelsson discloses a catheter assembly comprising a wetting fluid in sachet 6 (Page 10, lines 15-19); a catheter 3 having on its surface, on at least an insertable part thereof, a hydrophilic surface layer ('937, Page 6, lines 28-31, Page 10, lines 1-20); and a receptacle in the form of a receptacle 1 enclosing at least the insertable part of the catheter (Abstract). With regard to the limitation "providing low-friction surface character of the catheter by treatment with said wetting fluid", such a limitation constitutes functional language that is given little patentable weight herein. As Israelsson discloses a catheter with a hydrophilic surface layer and a wetting fluid that contacts said layer, a low-friction surface character of the catheter by treatment with said wetting fluid is necessarily provided. The wetting fluid comprises saline, which by its nature contains a dissolved osmolality-increasing compound such as sodium or potassium chloride. However Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/$dm^3$. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/$dm^3$).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-

increasing compound (NaCl) at a total concentration exceeding 600 mOsm/dm$^3$ when the fluid is separate from at least the insertable part of the catheter.

With respect to **claim 3:** The assembly disclosed by Israelsson presents a storage state in which the wetting fluid is kept separated in sachet 6 from the hydrophilic surface layer of the catheter, and an activation state in which the wetting fluid is released form the sachet and brought into contact with said hydrophilic surface layer before an intended use of the catheter. ('937, Abstract)

With respect to **claims 4, 18, 24, 30 and 34:** Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm$^3$. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm$^3$), which meets the narrower limitation of claims 4, 18, 24, 30 and 34, i.e. "preferably exceeds 800 mOsm/dm$^3$. The motivation to modify the Israelsson assembly such that the saline wetting fluid is the hypertonic saline solution disclosed by Bongard is stated *supra* with respect to claim 1.

With respect to **claims 6, 20 and 26:** Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm$^3$. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm$^3$), which meets the limitation of claims 4, 18, 24, 30 and 34, i.e. "less than 1,500 mOsm/dm$^3$), . The motivation to modify the Israelsson assembly such that the

saline wetting fluid is the hypertonic saline solution disclosed by Bongard is stated *supra* with respect to claim 1.

With respect to **claims 5,19,25,31,35:** The device of Israelsson as modified by Bongard has a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration of 1,026 mOsm/$dm^3$ when the fluid is separate from at least the insertable part of the catheter, which is not in the range of 850-950 mOsm/$dm^3$. However applicant has not established any criticality for this particular range. The osmolality increasing compound concentration is a result-effective variable in that it dictates the rate and direction of diffusion of the compound. Thus this range is considered herein to be an optimization of a result-effective variable. Since hypertonic saline is any saline solution with NaCl concentration greater than 0.9%, and a 0.9% NaCl concentration corresponds to an osmolality substantially equal to urine, any hypertonic saline solution having an NaCl concentration lower than the 3% disclosed by Bongard but greater than 0.9% would still be hypertonic and thus effective to treat hyponatremia and lubricate the catheter. One of ordinary skill in the art could reasonably expect that there are hypertonic saline solutions with an NaCl concentration in this range of greater than 0.9% - 3% that also have a total concentration of osmolality-increasing compound within the claimed range, rendering claims 5, 19, 25, 31 and 35 unpatentable.

With respect to **claim 16:** The catheter assembly disclosed by Israelsson '937 meeting all of the structural limitations of claim 1 and further comprises a separate wetting fluid container, sachet 6, which encloses said wetting fluid and which forms part of said catheter assembly. (Fig. 1, Page 10, lines 15-20)

13. Claims 1, 2, 7-15, 21-23, 27-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israelsson (WO 00/47494 A1) in view of Bongard.

With respect to **claim 1:** Israelsson discloses a catheter assembly comprising the following: a catheter 7 having on its surface, on at least an insertable part thereof, a hydrophilic surface layer providing low-friction surface character of the catheter by treatment with a wetting fluid 9, i.e. water (Abstract, Page 10, lines 3-7); and a receptacle 5 enclosing at least the insertable part of the catheter (Fig. 1, Page 10, lines 2-7). Israelsson discloses that the catheter is a catheter according to EP 217771 A1 to Johansson. This is interpreted herein as an incorporation by reference of the teachings of the Johansson reference. Johansson discloses a catheter having a hydrophilic surface layer that is treated with a 2% w/v saline solution (NaCl) comprises at least one dissolved osmolality-increasing compound, sodium chloride (NaCl), wherein the total concentration of the dissolved osmolality-increasing compound based on Johansson's disclosure of 2% w/v NaCl. That is there are (2 g NaCl/100 ml water)*(1/58.44 g/mol), or 0.34 mol/L NaCl. From this, there are 0.68 mOsm/L, since NaCl has two ions per molecule affecting osmotic pressure. Thus the concentration of the osmolality-increasing compound is 0.680 $mOsm/dm^3$, which does not fall within the claimed range. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 $mOsm/dm^3$).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and

treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is instead a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration exceeding 600 mOsm/$dm^3$ when the fluid is separate from at least the insertable part of the catheter.

With respect to **claim 2:** The wetting fluid disclosed by Israelsson by reference to Johansson is arranged in wetting contact with the hydrophilic surface layer of the catheter in cavity 5 for preservation of the hydrophilic surface layer in a wetted state during accommodation in said receptacle and provision of a ready-to-use catheter assembly. (Page 10, lines 2-7; '771, Page 3, lines 14-18)

With respect to **claim 7:** Israelsson discloses by reference to Johansson that said osmolality-increasing compounds is/are selected from the group consisting of urea, amino acids, mono and disaccharides, sugar alcohols, and non-toxic organic and inorganic salts or acids, polypeptides and mixtures thereof. ('771, Abstract)

With respect to **claim 8:** Israelsson discloses by reference to Johansson that said osmolality-increasing compound is sodium chloride. ('771, Abstract)

With respect to **claim 9:** Israelsson discloses by reference to Johansson that the osmolaltiy increasing compound, and thus the wetting fluid, when the compound comes in contact with the

water in cavity 5, further comprises a polymer. (‘771.Abstract)

With respect to **claim 10:** The polymer disclosed by Israelsson by reference to Johansson is a hydrophilic polymer, and preferably the same type of hydrophilic polymer as in the hydrophilic coating of the catheter. (‘771, Page 2, lines 46, 47)

With respect to **claim 11:** The amount of polymer disclosed by Israelsson by reference to Johansson, PVP, is present in a wetting fluid in an amount of 5% w/v. Since the solvent is water (density=100 g/100 mL), the PVP is present in an amount of 5 g PVP/100 g water, which falls within the claimed range of 0-20% of weight. and most preferably in the range 5-15%, and typically about 10%.

With respect to **claim 12:** The wetting fluid 9 disclosed by Israelsson by reference to Johansson having the osmolality-increasing compound therein is a sterile aqueous solution, i.e. it is a water-based liquid.

With respect to **claim 13:** The catheter 7 disclosed by Israelsson is a urinary catheter. With regard to the limitation "intended for intermittent use”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus since Israelsson meets the limitation of a urinary catheter and no additional structure is claimed, the catheter of Israelsson meets this limitation regarding intended use as well.

With respect to **claim 14:** The wetting receptacle 5 disclosed by Israelsson encloses the entire catheter. (Fig. 1)

With respect to **claim 15:** The receptacle 5 is formed by sealing packaging material layers around the catheter, forming a cavity where the wetting fluid will later be housed, thus the receptacle necessarily entirely encloses said wetting fluid. (Page 9, line 34 – Page 10, line 7)

With respect to **claim 21:** Israelsson discloses by reference to Johansson that said osmolality-increasing compounds is/are selected from the group consisting of urea, amino acids, mono and disaccharides, sugar alcohols, and non-toxic organic and inorganic salts or acids, polypeptides and mixtures thereof. ('771, Abstract)

With respect to **claim 22:** The wetting fluid 9 disclosed by Israelsson by reference to Johansson having the osmolality-increasing compound therein is a sterile aqueous solution, i.e. it is a water-based liquid.

With respect to **claim 23:** Israelsson discloses a method for producing a catheter assembly, comprising: providing a receptacle, cavity 5 (Page 10, lines 2-7); providing a hydrophilic catheter 7 (Abstract); providing a fluid 9 that interacts with the catheter hydrophilic coating to comprise an osmolality-increasing compound meeting the limitation of a wetting fluid (taught by reference to Johansson '771); arranging at least an insertable part of the catheter in the receptacle 5 (Fig. 1) and arranging said wetting fluid by placing the fluid in receptacle 5 as a part of said catheter assembly; said wetting fluid, upon contact with the hydrophilic coating of the catheter 7, comprising at least one dissolved osmolality-increasing compound, i.e. sodium chloride. The

concentration of the osmolality-increasing compound in the Johansson solution is 0.680 mOsm/dm$^3$, which does not fall within the claimed range. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm$^3$).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is instead a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration exceeding 600 mOsm/dm$^3$ when the fluid is separate from at least the insertable part of the catheter.

With respect to **claim 27:** Israelsson discloses by reference to Johansson that said osmolality-increasing compounds is/are selected from the group consisting of urea, amino acids, mono and disaccharides, sugar alcohols, and non-toxic organic and inorganic salts or acids, polypeptides and mixtures thereof. (‘771, Abstract)

With respect to **claim 28:** The wetting fluid 9 disclosed by Israelsson by reference to Johansson having the osmolality-increasing compound therein is a sterile aqueous solution, i.e. it is a water-based liquid.

With respect to **claim 29:** Israelsson discloses, by reference to Johansson, a catheter 7 having on its surface, on at least an insertable part thereof, a hydrophilic surface layer for producing a low-friction surface character of the catheter by treatment with a wetting fluid, characterized in that the hydrophilic coating when wetted in preparation for an intended use incorporates at least one osmolality-increasing compound, namely sodium chloride. The concentration of the osmolality-increasing compound in the Johansson solution is 0.680 mOsm/$dm^3$, which does not fall within the claimed range. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/$dm^3$).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is instead a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration

exceeding 600 mOsm/$dm^3$ when the fluid is separate from at least the insertable part of the catheter.

With respect to **claim 32:** The catheter 7 disclosed by Israelsson is a urinary catheter. With regard to the limitation "intended for intermittent use", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus since Israelsson meets the limitation of a urinary catheter and no additional structure is claimed, the catheter of Israelsson meets this limitation regarding intended use as well.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761